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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 3853, P. 004 568056	Submission to enter the national stage under 35 U.S.C. § 371.
INTERNATIONAL APPLICATION NO. PCT/GB2004/003520	INTERNATIONAL FILING DATE 13 August 2004	PRIORITY DATE CLAIMED 14 August 2003	
TITLE OF INVENTION Ostomy/Fistula Bag			
APPLICANT(S) FOR DO/EO/US Thomas G. Eakin			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☒ The US has been elected (Article 31).
- ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - ☒ is attached hereto (required only if not communicated by the International Bureau).
 - ☐ has been communicated by the International Bureau.
 - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
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 - ☐ is attached hereto.
 - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - ☐ are attached hereto (required only if not communicated by the International Bureau).
 - ☐ have been communicated by the International Bureau.
 - ☒ have not been made; however, the time limit for making such amendments has NOT expired.
 - ☐ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
- ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☒ A preliminary amendment.
- ☐ An Application Data Sheet under 37 CFR 1.76.
- ☐ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
- ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

1AP20 Rec'd PCT/PTO 10 FEB 2006

PTO-1390 (Rev. 07-2005)

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 1.5em; font-weight: bold;">10/568006</div>		INTERNATIONAL APPLICATION NO. PCT/GB2004/003520		ATTORNEY'S DOCKET NUMBER 3853 P 004	
20. Other items or information: <div style="text-align: center; padding-top: 10px;">Please see attached sheet.</div>					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$ 200.00	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations..... \$200				\$ 500.00	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400 All other situations..... \$500				\$ 1000.00	
TOTAL OF 21, 22 and 23 =				\$1000.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.				\$ 0	
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	\$ 0	
51 - 100 =	/50 =		x \$250	\$ 130.00	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$ 100.00	
Total claims	22 - 20 =	2	x \$ 50	\$ 0	
Independent claims	3 - 3 =	0	x \$200	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$ 0	
TOTAL OF ABOVE CALCULATIONS =				\$1230.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$ 0	
SUBTOTAL =				\$ 0	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$ 0	
TOTAL NATIONAL FEE =				\$ 0	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 0	
TOTAL FEES ENCLOSED =				\$	
Amount to be refunded:				\$	
Amount to be charged				\$	

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NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

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No. 31,882

REGISTRATION NUMBER

10/568006

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Item No. 20: Other items or information:

Copy of Specification (9 pages), Claims (4 pages), and Drawings (7 pages)
(Application as published with the PCT as International Publication Number
WO 2005/016158 A1).

Replacement Sheet with Figs 4A and 4B.

Annotated Sheet Showing Changes (added label for 4B)

Copy of 7 sheets of Formal Drawings (Figs. 1-3, 4A, 4B, 5A, 5B, 6A, 6B, 7A, 7B,
8A, 8B).

Copy of cover sheet of International Publication Number WO 2005/016158 A1.

Copy of International Search Report for Application No. GB 2004/003520 dated 25
November 2004.

Copy of Written Opinion of the International Searching Authority.

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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 3853 P 006 006 568056 10
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		

INTERNATIONAL APPLICATION NO. PCT/GB2004/003520	INTERNATIONAL FILING DATE 13 August 2004	PRIORITY DATE CLAIMED 14 August 2003
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Submission to enter the national stage under 35 U.S.C. § 371.

TITLE OF INVENTION Ostomy/Fistula Bag

APPLICANT(S) FOR DO/EO/US Thomas G. Eakin

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10/568006		PCT/GB2004/003520		3853 P 004	
20. Other items or information: <p style="margin-left: 40px;">Please see attached sheet.</p>					
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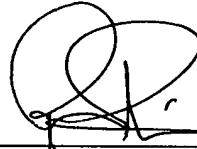
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10/568006

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Submission to
enter the
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under 35 U.S.C.

1AP20 Rec'd PCT/PTO 10 FEB 2006

Attorney Docket No. 3853 P 004

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
U.S. NATIONAL FILING UNDER 35 U.S.C. § 371**

In Re U.S. Utility Patent Application of:
Thomas G. Eakin

From: PCT/GB2004/003520 (filed 13 August 2004)
British Application No. GB 0319139.2 (filed 14 August 2003)

For: Ostomy/Fistula Bag

Mailed:

PRELIMINARY AMENDMENT

Commissioner for Patents
Mail Stop PCT (U.S. National)
P.O. Box 1450
Alexandria, Virginia 22313-1450

Before examination of this Application, please make the following amendments.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the claims are reflected in the listing of claims which begins on page 4 of
this paper.

The Abstract to be added is on page 7 of this paper.

Amendment to the Drawings is on page 8 of this paper.

Remarks are on page 9 of this paper.

In The Specification:

On Page 1, after the title, please insert the following heading: --DESCRIPTION--.

On Page 1, after the above heading, please insert the following heading: --CROSS-REFERENCE TO RELATED APPLICATIONS--.

On Page 1, after the above heading, please insert the following paragraph: --This Application is a U.S. National filing under § 371 of International Application No. PCT/GB2004/003520, with an international filing date of August 13, 2004, now pending, claiming priority from Great Britain Application No. GB2003/19139.2, with a filing date of August 14, 2003, now pending, and herein incorporated by reference.--

On Page 1, after the above added new heading and paragraph are added, please add the heading: --TECHNICAL FIELD--.

On Page 1, after line 7, please add the heading: --BACKGROUND OF THE INVENTION--.

On Page 2, after line 2, please add the heading --SUMMARY OF THE INVENTION--.

On Page 3, after line 5, please add the heading --BRIEF DESCRIPTION OF THE DRAWINGS--.

On Page 3, line 12, please replace the paragraph with the following amended paragraph: ~~Figure 4 is a diagram~~ Figures 4A and 4B are diagrams illustrating the manner in which the seal may be operated in the embodiment of Figure 3;

On Page 3, line 14, please replace the paragraph with the following amended paragraph: ~~Figure 5 is a diagram~~ Figures 5A and 5B are diagrams illustrating a further embodiment of the present invention;

On Page 3, line 16, please replace the paragraph with the following amended paragraph: ~~Figure 6 is a diagram~~ Figures 6A and 6B are diagrams illustrating the manner in which the seal operates in the embodiment of figure 5 of the present invention;

On Page 3, line 18, please replace the paragraph with the following amended paragraph: ~~Figure 7 shows a~~ Figures 7A and 7B show yet further embodiments of the present invention; ~~and~~ and.

On Page 3, line 19, please replace the paragraph with the following amended paragraph: ~~Figure 8 shows~~ Figures 8A and 8B show yet ~~another~~ other embodiments of the present invention.

Attorney Docket No. 353 P 004
Title: Ostomy/Fistula Bag
Page 3

On Page 3, after line 20, please add the heading --DETAILED DESCRIPTION OF THE
INVENTION--.

Amendments in The Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

What is claimed is:

1. (currently amended) A lesion or fistula isolating bag, ~~the bag defining~~ comprising: a first chamber having a closeable ~~entrance and~~ entrance; a second chamber for application to a lesion or ~~fistula and~~ fistula, wherein access to the second chamber is made through the first chamber via a valve, ~~the valve being~~ arranged to inhibit passage of fluid from the second chamber to the first~~[[,]]~~ and to allow said access from the first chamber to the second~~[[,]]~~; and, the bag further comprising a closure for said closeable entrance.
2. (original) A bag according to claim 1, wherein the closeable entrance is sealable.
3. (currently amended) A bag according to claim 1 ~~or claim 2~~, wherein said valve includes at least two members which extend inside the bag and, when the closure is in a closed state, said members close to form the valve.
4. (currently amended) A bag according to claim 1 ~~or claim 2~~, wherein the valve comprises a flexible partition dividing the first and second chambers ~~(114, 116), the partition and~~ comprising first and second adjacent layers ~~(120, 122), and wherein~~ with each layer ~~includes~~ including an aperture ~~(124, 126), the respective apertures being offset one from the other.~~
5. (currently amended) A lesion or fistula isolating bag ~~(110) comprising~~: first and second chambers ~~(114, 116), one of which has a closeable opening (118) for access, wherein the chambers are divided by a flexible partition, the partition comprising~~ first and second adjacent layers ~~(120, 122), and wherein~~ with each layer ~~includes~~ including an aperture ~~(124, 126), the respective apertures being offset one from the other.~~
6. (currently amended) A bag according to claim 4 ~~or claim 5~~ in which each aperture comprises a respective slit.
7. (original) A bag according to claim 6 in which the slits extend generally parallel to one another.
8. (currently amended) A bag according to ~~any one of claims 4 to 7~~ claim 4, wherein the first layer is formed of a material which is heavier than the material of the second layer.

9. (currently amended) A bag according to ~~any one of claims 4 to 8~~ claim 4, wherein one layer is thicker than the other.
10. (currently amended) A bag according to ~~any one of claims 6 to 9~~ claim 6, wherein the offset between the slits is between ~~100 mm and 5 mm, preferably between 50 mm and 10 mm, more preferably between 30 mm and 15 mm~~ 5 mm and 100 mm.
11. (currently amended) A bag according to ~~any one of claims 6 to 10~~ claim 6, wherein the slits are between 80 and 300 mm long.
12. (currently amended) A bag according to ~~any one of claims 4 to 11~~ claim 4, wherein the bag comprises first and second bag portions, the first chamber being formed by the first bag portion and the second chamber being formed by the second bag portion.
13. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein said closeable entrance is located on an outer edge of the first chamber .
14. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein the closure is a zip fastener.
15. (currently amended) A bag according to ~~any one of claims 1 to 13~~ claim 4, wherein the closure is a removable cover such as a lid.
16. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein the bag includes a further aperture for the passage of fluid between atmosphere and the device.
17. (original) A bag according to claim 16, wherein the further aperture comprises a drain.
18. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein an outer surface of the second chamber is adherent.
19. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein the first chamber has at least one overall dimension approximately equal to 50 mm.
20. (currently amended) A bag for isolating a lesion or fistula comprising:
 - a vessel comprising a first wall of flexible material, ~~the first wall including~~ with a first slit~~[[,]]~~ and a second wall opposite the first wall with ~~the vessel further including~~ a closeable opening ~~on a second wall, the second wall being opposite the first wall;~~
 - a bag including a second slit;

wherein the vessel and bag are joined with one another such that the first and second slits are oriented in the same direction and are adjacent to, but offset from, one another and the ~~join~~ joint surrounds an area encompassing the first and second slits.

21. (currently amended) ~~A method of making a bag according to any one of claims 1 to 20~~ A bag according to claim 1, wherein the bag ~~or bags are~~ is made from flexible polymers selected from a group consisting, for example, any of polyethylene, polyvinyl chloride and ethyl vinyl acetate.

22. (currently amended) ~~A method of making a~~ A bag according to claim 12, wherein there is a joint ~~the join~~ between the first and second bags and the joint is made by a welding process selected from the group consisting of, for example, any of thermal, radio-frequency and impulse welding.

23. (Cancelled)

In The Abstract:

After the claims, please insert the following Abstract:

-- A lesion or fistula isolating bag, the bag defining a first chamber having a closeable entrance and a second chamber for application to a lesion or fistula and wherein access to the second chamber is made through the first chamber via a valve, the valve being arranged to inhibit passage of fluid from the second chamber to the first, and to allow said access from the first chamber to the second, the bag further comprising a closure for said closeable entrance.--

Amendment in the Drawings:

The attached sheet of drawings includes changes to Figure 4B. This sheet, which includes Figures 4A and 4B, replaces the original sheet including Figure 4A. In Figure 4B, previously omitted labeling “4B” has been added.

REMARKS

The Specification has been amended to conform with the drawings.

The claims have been amended to conform to United States practice and to remove multiple dependencies; no new matter has been introduced by these amendments. Claim 23 has been cancelled. Consequently, claims 1-22 are to be examined.

Attached are a Replacement Sheet and an Annotated Sheet Showing the Change made to the Figures to correct an omission (Figure Number).

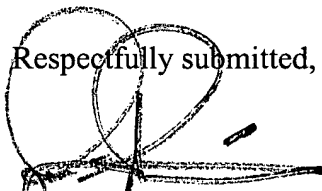
Applicant respectfully requests entry of the above amendments prior to examination.

Please charge any deficiencies of fees to Deposit Account No. 23-0280.

Respectfully submitted,

Date: 10 FEBRUARY 2006

By:



Roger H. Stein, Reg. PTO Reg. No. 31,882

CUSTOMER NUMBER 23424

Wallenstein Wagner & Rockey, LTD.

311 South Wacker Drive, 53rd Floor

Chicago, Illinois 60606-6630

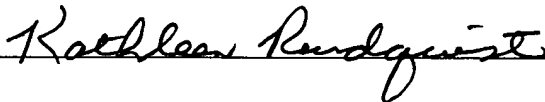
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From PCT/GB2004/003520 of: Thomas G. Eakin

For: Ostomy/Fistula Bag

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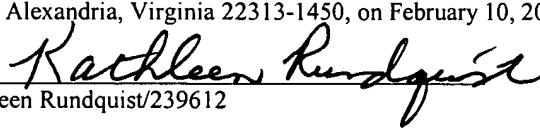
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Attorney Docket No.: 3853 P 004

Enclosures: Post Card.
Transmittal Letter to the U.S. Designated/Elected Office (DO/EO/US)
Concerning a Filing under 35 U.S.C. 371 (in duplicate).
Preliminary Amendment, in duplicate.
Copy of Specification (9 pages), Claims (4 pages), and Drawings (7 pages)
(Application as published with the PCT as International Publication
Number WO 2005/016158 A1).
Replacement Sheet with Figs 4A and 4B.
Annotated Sheet Showing Changes (added label for 4B)
Copy of 7 sheets of Formal Drawings (Figs. 1-3, 4A, 4B, 5A, 5B, 6A, 6B,
7A, 7B, 8A, 8B).
Copy of cover sheet of International Publication Number WO 2005/016158
A1.
Copy of International Search Report for Application No. GB 2004/003520
dated 25 November 2004.
Copy of Written Opinion of the International Searching Authority.

This is a 35 U.S.C. Section 371 U.S. National Filing from PCT International Application No.
PCT/GB2004/003520 filed 13 August 2004 claiming priority from GB 0319139.2 filed 14
August 2003.

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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
U.S. NATIONAL FILING UNDER 35 U.S.C. § 371**

In Re U.S. Utility Patent Application of:
Thomas G. Eakin

From: PCT/GB2004/003520 (filed 13 August 2004)
British Application No. GB 0319139.2 (filed 14 August 2003)

For: Ostomy/Fistula Bag

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PRELIMINARY AMENDMENT

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Before examination of this Application, please make the following amendments.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the claims are reflected in the listing of claims which begins on page 4 of
this paper.

The Abstract to be added is on page 7 of this paper.

Amendment to the Drawings is on page 8 of this paper.

Remarks are on page 9 of this paper.

In The Specification:

On Page 1, after the title, please insert the following heading: --DESCRIPTION--.

On Page 1, after the above heading, please insert the following heading: --CROSS-REFERENCE TO RELATED APPLICATIONS--.

On Page 1, after the above heading, please insert the following paragraph: --This Application is a U.S. National filing under § 371 of International Application No. PCT/GB2004/003520, with an international filing date of August 13, 2004, now pending, claiming priority from Great Britain Application No. GB2003/19139.2, with a filing date of August 14, 2003, now pending, and herein incorporated by reference.--

On Page 1, after the above added new heading and paragraph are added, please add the heading: --TECHNICAL FIELD--.

On Page 1, after line 7, please add the heading: --BACKGROUND OF THE INVENTION--.

On Page 2, after line 2, please add the heading --SUMMARY OF THE INVENTION--.

On Page 3, after line 5, please add the heading --BRIEF DESCRIPTION OF THE DRAWINGS--.

On Page 3, line 12, please replace the paragraph with the following amended paragraph: ~~Figure 4 is a diagram~~ Figures 4A and 4B are diagrams illustrating the manner in which the seal may be operated in the embodiment of Figure 3;

On Page 3, line 14, please replace the paragraph with the following amended paragraph: ~~Figure 5 is a diagram~~ Figures 5A and 5B are diagrams illustrating a further embodiment of the present invention;

On Page 3, line 16, please replace the paragraph with the following amended paragraph: ~~Figure 6 is a diagram~~ Figures 6A and 6B are diagrams illustrating the manner in which the seal operates in the embodiment of figure 5 of the present invention;

On Page 3, line 18, please replace the paragraph with the following amended paragraph: ~~Figure 7 shows a~~ Figures 7A and 7B show yet further embodiments of the present invention; ~~and~~ and,

On Page 3, line 19, please replace the paragraph with the following amended paragraph: ~~Figure 8 shows~~ Figures 8A and 8B show yet ~~another~~ other embodiments of the present invention.

Attorney Docket No. 353 P 004

Title: Ostomy/Fistula Bag

Page 3

On Page 3, after line 20, please add the heading --DETAILED DESCRIPTION OF THE INVENTION--.

Amendments in The Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

What is claimed is:

1. (currently amended) A lesion or fistula isolating bag, ~~the bag defining~~ comprising: a first chamber having a closeable ~~entrance and~~ entrance; a second chamber for application to a lesion or ~~fistula and~~ fistula, wherein access to the second chamber is made through the first chamber via a valve, ~~the valve being~~ arranged to inhibit passage of fluid from the second chamber to the first~~[[,]]~~ and to allow said access from the first chamber to the second~~[[,]]~~; ~~and, the bag further comprising~~ a closure for said closeable entrance.
2. (original) A bag according to claim 1, wherein the closeable entrance is sealable.
3. (currently amended) A bag according to claim 1 ~~or claim 2~~, wherein said valve includes at least two members which extend inside the bag and, when the closure is in a closed state, said members close to form the valve.
4. (currently amended) A bag according to claim 1 ~~or claim 2~~, wherein the valve comprises a flexible partition dividing the first and second chambers ~~(114, 116), the partition and~~ comprising first and second adjacent layers ~~(120, 122), and wherein with~~ each layer ~~includes~~ including an aperture ~~(124, 126), the respective apertures being offset one from the other.~~
5. (currently amended) A lesion or fistula isolating bag ~~(110)~~ comprising: first and second chambers ~~(114, 116)~~, one of which has a closeable opening ~~(118)~~ for access, wherein the chambers are divided by a flexible partition, ~~the partition comprising~~ first and second adjacent layers ~~(120, 122), and wherein with~~ each layer ~~includes~~ including an aperture ~~(124, 126), the~~ respective apertures being offset one from the other.
6. (currently amended) A bag according to claim 4 ~~or claim 5~~ in which each aperture comprises a respective slit.
7. (original) A bag according to claim 6 in which the slits extend generally parallel to one another.
8. (currently amended) A bag according to ~~any one of claims 4 to 7~~ claim 4, wherein the first layer is formed of a material which is heavier than the material of the second layer.

9. (currently amended) A bag according to ~~any one of claims 4 to 8~~ claim 4, wherein one layer is thicker than the other.
10. (currently amended) A bag according to ~~any one of claims 6 to 9~~ claim 6, wherein the offset between the slits is between ~~100 mm and 5 mm, preferably between 50 mm and 10 mm, more preferably between 30 mm and 15 mm~~ 5 mm and 100 mm.
11. (currently amended) A bag according to ~~any one of claims 6 to 10~~ claim 6, wherein the slits are between 80 and 300 mm long.
12. (currently amended) A bag according to ~~any one of claims 4 to 11~~ claim 4, wherein the bag comprises first and second bag portions, the first chamber being formed by the first bag portion and the second chamber being formed by the second bag portion.
13. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein said closeable entrance is located on an outer edge of the first chamber.
14. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein the closure is a zip fastener.
15. (currently amended) A bag according to ~~any one of claims 1 to 13~~ claim 4, wherein the closure is a removable cover such as a lid.
16. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein the bag includes a further aperture for the passage of fluid between atmosphere and the device.
17. (original) A bag according to claim 16, wherein the further aperture comprises a drain.
18. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein an outer surface of the second chamber is adherent.
19. (currently amended) A bag according to ~~any one of the preceding claims~~ claim 4, wherein the first chamber has at least one overall dimension approximately equal to 50 mm.
20. (currently amended) A bag for isolating a lesion or fistula comprising:
 - a vessel comprising a first wall of flexible material, ~~the first wall including~~ with a first slit[,], and a second wall opposite the first wall with ~~the vessel further including~~ a closeable opening ~~on a second wall, the second wall being opposite the first wall;~~
 - a bag including a second slit;

wherein the vessel and bag are joined with one another such that the first and second slits are oriented in the same direction and are adjacent to, but offset from, one another and the ~~join~~ joint surrounds an area encompassing the first and second slits.

21. (currently amended) ~~A method of making a bag according to any one of claims 1 to 20~~ A bag according to claim 1, wherein the bag ~~or bags are~~ is made from flexible polymers selected from a group consisting, for example, any of polyethylene, polyvinyl chloride and ethyl vinyl acetate.

22. (currently amended) ~~A method of making a~~ A bag according to claim 12, wherein there is a joint ~~the join~~ between the first and second bags and the joint is made by a welding process selected from the group consisting of, for example, any of thermal, radio-frequency and impulse welding.

23. (Cancelled)

In The Abstract:

After the claims, please insert the following Abstract:

-- A lesion or fistula isolating bag, the bag defining a first chamber having a closeable entrance and a second chamber for application to a lesion or fistula and wherein access to the second chamber is made through the first chamber via a valve, the valve being arranged to inhibit passage of fluid from the second chamber to the first, and to allow said access from the first chamber to the second, the bag further comprising a closure for said closeable entrance.--

Attorney Docket No. 353 P 004
Title: Ostomy/Fistula Bag
Page 8

Amendment in the Drawings:

The attached sheet of drawings includes changes to Figure 4B. This sheet, which includes Figures 4A and 4B, replaces the original sheet including Figure 4A. In Figure 4B, previously omitted labeling “4B” has been added.

REMARKS

The Specification has been amended to conform with the drawings.

The claims have been amended to conform to United States practice and to remove multiple dependencies; no new matter has been introduced by these amendments. Claim 23 has been cancelled. Consequently, claims 1-22 are to be examined.

Attached are a Replacement Sheet and an Annotated Sheet Showing the Change made to the Figures to correct an omission (Figure Number).

Applicant respectfully requests entry of the above amendments prior to examination.

Please charge any deficiencies of fees to Deposit Account No. 23-0280.

Respectfully submitted,

Date: 10 FEBRUARY 2006

By: 

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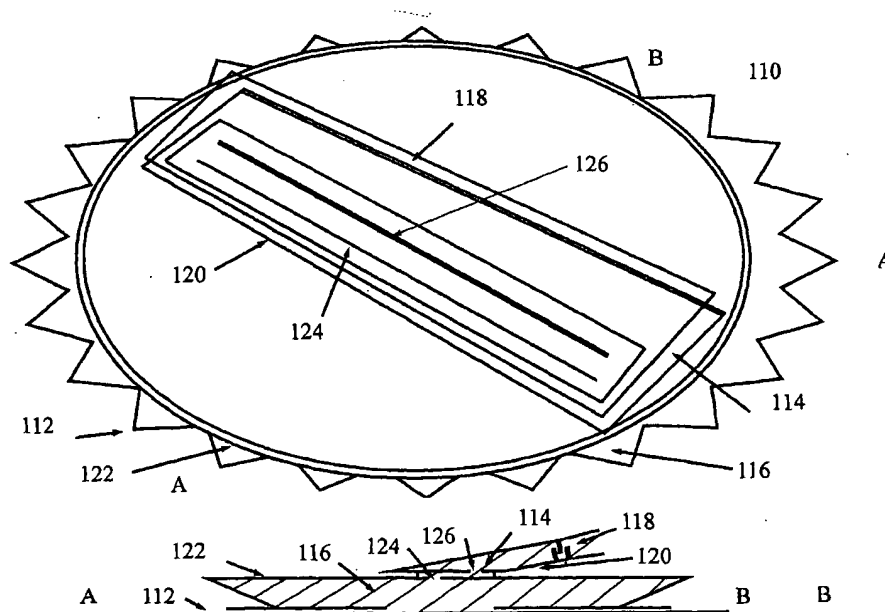
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(54) Title: OSTOMY/FISTULA BAG



(57) Abstract: A lesion or fistula isolating bag, the bag defining a first chamber having a closeable entrance and a second chamber for application to a lesion or fistula and wherein access to the second chamber is made through the first chamber via a valve, the valve being arranged to inhibit passage of fluid from the second chamber to the first, and to allow said access from the first chamber to the second, the bag further comprising a closure for said closeable entrance.

WO 2005/016158 A1

Ostomy/Fistula Bag

5 The present invention relates to devices for providing access to a lesion – such as an ostomy or wound – or to a fistula on a person or animal (hereinafter generically referred to as a “wound”) whilst isolating the wound from a surrounding environment. More specifically, the invention relates to an ostomy, fistula or wound drainage bag for this purpose.

10 Various devices are known for the dressing of wounds on persons or animals which simultaneously allow access to the wound for inspection and/or for treatment whilst isolating the wound from the surrounding atmosphere. For example, a device known in the art is shown in Figure 1. The device 10, sometimes known as a window bag, is applied to the skin of the patient 12 over the wound 18. The device consists of a body 14 which is often of generally
15 circular cross-section and has a lid 16 which may be removably fixed to the body 14 to isolate the wound from the surrounding environment. Access to the wound may be made by removing the lid 16. These lids and bodies are of generally circular cross-section as the shape tends to allow a more efficient seal when compared to lids and bodies of other shapes.

20 Another type of device that is known in the art is disclosed in United States Design Patent No. 432,232. This document discloses a wound drainage device which allows access and isolation for the wound and includes a zip fastener access for this purpose.

25 Such devices have several inherent disadvantages. These include the fact that the seals are not particularly efficient; i.e. the zip of US Design Patent No. 432,232 may not be particularly water tight. Further, neither device offers

efficient isolation of the wound from the surrounding atmosphere if the lid is not properly sealed.

It is an object of the present invention at least to alleviate these problems.

5

The invention is set out in the claims.

Embodiments of the present invention provide advantages over the prior art by providing a bag device with first and second chambers and a seal, or valve,
10 between the chambers which inhibits the passage of fluid between the chambers but also allows access for inspection and/or treatment of the wound. In one embodiment of the present invention, this is achieved by providing two or more members which extend inside the bag from its opening and which close to form the valve. In another embodiment of the present invention, the
15 valve is effected by providing a flexible partition which divides the chambers. Access is made to the second chamber from the first chamber through the flexible partition which has two layers, each layer having a respective slit which is offset from the other. Such an arrangement offers effectively a “zig-zag” set up which is the extra “seal” or “valve” in the device and therefore
20 extra protection for the patient’s wound. It would of course be possible to extend this arrangement so that the flexible partition has more than two layers, each layer having its own slit.

A further advantage of the present invention is that embodiments may be
25 automatically manufactured using machinery. Many of the devices in the prior art must be manufactured by hand.

Applications of the device of the present invention include application to a wound as defined above. In such an application utilising embodiments of the

present invention, the bag is fixed to a patient over a wound that he or she has. The user (a doctor or nurse) may open the bag at the entrance and enter his/her hand into the bag and the first chamber. Access can be gained to the wound for inspection and/or further treatment of the wound through the valve and the
5 second chamber.

Embodiments of the present invention will now be described, by way of example only, and with reference to the accompanying drawings in which:
Figure 1 is a diagram showing a window bag as known in the prior art;
10 Figure 2 is a diagram showing an embodiment of the present invention;
Figure 3 is a diagram showing another embodiment of the present invention;
Figure 4 is a diagram illustrating the manner in which the seal may be operated in the embodiment of Figure 3;
Figure 5 is a diagram illustrating a further embodiment of the present
15 invention;
Figure 6 is a diagram illustrating the manner in which the seal operates in the embodiment of figure 5 of the present invention;
Figure 7 shows a yet further embodiment of the present invention; and
Figure 8 shows yet another embodiment of the present invention.

20

Referring now to Figure 2 an embodiment of the present invention is illustrated. The bag 4 comprises an opening or entrance 6, chambers 7a and 7b and a valve 9 which isolates one chamber from the other. The bag is placed over the wound 8 of the patient 2 and the user enters his or her hand through
25 the bag entrance 6 into the first chamber 7a. The valve 9 opens, or access is gained through it, for the user to inspect or treat the wound. Operation of the valve 9, which may take several forms, is discussed below.

Referring now to Figure 3, a device 110 according to an embodiment of the present invention is illustrated. The device 110 comprises first and second chambers 114, 116 and a closeable aperture 118 which may be provided by a lid, zip fastener or other suitable closure means. The two chambers 114, 116 are separated by a partition comprising two adjacent layers 120, 122 each of which has a respective slit 124, 126. As is illustrated, the slits may be oriented in the same direction, but offset from one another. The slits need not be parallel to one another, but may simply be oriented in substantially the same direction. It will also be appreciated that the openings in the layers need not be by means of slits, but may be by any suitable shape of opening.

In use, the device 110 is affixed to a patient's skin 112 and over a wound thereon (not shown). An outer surface of the device is adherent (for example, the outer surface may be coated in adhesive) in order to affix or attach it to a patient. Coating the outer surface of the chamber with adhesive offers a convenient and easy method of fixing the device to the patient. Preferably, the adhesive is of a type approved for medical use such that it does not irritate the patient's skin or provide any risk of infection to the wound.

In an embodiment of the invention, the first layer 120 of the partition may be heavier than the second layer 122. In this way, the forming of the seal/valve when the user's hand is withdrawn from the device is enhanced; the additional weight of the first layer of the partition presses down on the second layer such that it presses close against the patient's body thereby forming the seal. Various means may be used to achieve this additional weight in the first layer, for example, it may be formed of a material which is more dense than the material of the second layer, and/or the material of the first layer is of greater thickness than the material of the second layer.

In embodiments of the present invention the closeable aperture 118 in the first chamber is sealable, so that the aperture 118 is watertight. In other embodiments of the invention, the aperture is sealable so that it is airtight thereby increasing the sterility of the device.

5

In embodiments of the present invention the device is made from flexible polymer, for example, any of polyethylene (PE), polyvinyl chloride (PVC) and ethyl (or ethylene) vinyl acetate (EVA). Such polymers offer flexible and convenient-to-manufacture materials for the construction of the chambers or bag. Typically, the first layer 120 of the partition (or first chamber itself) is constructed from PE and the second layer 122 of the partition (or second chamber itself) is constructed from EVA. Other olefins or polyolefins might also be used. In this instance, PE is a slightly heavier material than EVA and, as such, assists the forming of the seal as described above.

15

In an embodiment of the present invention, the offset between the slits is between 15 to 30mm. However, the offset between the slits may be between 5 mm and 100 mm or between 10 mm and 50 mm.

20

In an embodiment of the invention, the slits 124 and 126 are between 80 mm and 300 mm long depending on the overall size of the device. It has been found that slit lengths in this range offer convenient access without compromising the integrity of the seal offered by the partition.

25

Referring now to Figure 4 the manner in which the seal operates and in which a user may gain access to a wound through the device is now discussed. Figure 4a shows a cutaway of the device 110 illustrating the layers 120 and 122 in relation to the patient's skin 112. The wound on the patient's skin is not shown for the sake of clarity. Also shown in the first layer 120 is the slit 124 and in

the second layer 122 is shown the slit 126. As mentioned above, these slits are offset from one another. The user gains access to the first chamber 114 by opening the closeable aperture 118 which is shown in Figure 3. The user then opens the slit 124 which opens as shown in Figure 4b as the layer is made of a flexible polymer and then accesses the opening by pushing through in the direction 128 as shown and then through the slit 126. As the second layer 122 is also made from flexible polymer, as discussed above, the user has access directly through both layers to the wound for inspection and/or treatment.

Referring now to Figure 5, another embodiment of the present invention is now discussed. In this embodiment 210 of the device the first and second chambers are formed by the joining together of two bags or bag portions 214, 216. The two bags 214, 216 are welded together at 230 as shown in Figure 5b. Various methods of welding may be employed for this purpose, the most suitable having been found to be thermal welding, radio-frequency welding or impulse welding.

In this embodiment, the width of the bag (dimension 234 as shown in Figure 5a) is approximately 50 mm. A bag of this size offers sufficient width for the user to manipulate the chamber or bag to open it, and access the slits 224, 226 in order to access to the patient's wound. Of course, it will be appreciated that other dimensions of this magnitude, say between 200 and 20 mm, or between 150 and 25 mm, or 100 and 30mm, or 75 and 40 mm may be used depending on the requirements of the particular application.

The closeable aperture 218 is formed by means of a plastic (or other suitable material) zip fastener which offers convenient closeable access to the first bag. Plastic zip fasteners on their own are inefficient at providing fluid containment, but coupled with the seal/valve offered by the flexible partition with offset slits,

the device offers a secure seal to contain any fluid which may be discharged by the patient's wound.

5 Alternatively, and as mentioned in the preceding example, the closeable aperture is effected by a removable cover such as a lid. Any other type of closing may be used such as button fasteners, but it is preferable that the aperture is sealable.

10 As mentioned above, the two bags are welded together around the slits at 230. The zipper weld may be inset to allow the zipper the freedom to be opened easily by the user as shown at 236.

15 The width of the first bag (zipper bag) is determined such that it suits the dimensions of the second bag (wound bag).

The slit 224 in the first bag 214 should be at the bottom of the first bag while the slit 226 in the second bag 216 is situated close to the weld adjacent to the zip 214.

20 In embodiments of the present invention a further aperture 232 may be provided in device 210. Multiple further apertures may be provided but a single aperture 232 is illustrated for the sake of simplicity. This aperture (or apertures) may be multi-purpose in that it could be used for the draining of any fluid which is discharged by the wound, for wound irrigation or, could possibly
25 be used for sterile access to the wound, for, for example, an intravenous drip to the patient.

The manner in which access may be effected to the patient's wound with an alternative embodiment is now illustrated in Figure 6. The slits 224, 226 are

shown in the first and second bags 214, 216. When a user inserts his or her hand through the aperture 218 (the zipper aperture 218 as shown open in Figure 6), the action of raising the aperture 218 causes the layer 220 of the bag to move in the manner illustrated in Figure 6b. Access may then be made to the second bag 216 in the direction 228 as shown.

Figure 7 illustrates a further alternative embodiment of the present invention which shows an alternative version of the valve of Figures 3 to 6. In this embodiment the zip 318 is situated on an outside edge of the bag 314, in this case at the open top of the wound bag which is attached to the patient 316 over the wound 324. Each side of the zip strip is welded to the front and back of the bag respectively as shown at 330. The valve 334 is effected by members which extend away from the zip fastener into the bag 314 and is effective when the zip is closed. Access is obtained to the zip bag interior 314 through the open zip 318, the valve 334 so that the wound 324 may then be accessed. Such a valve which is integral with the zip 318 offers a further level of security to the device so that the likelihood of any leakage of wound discharge or of infection to the wound is greatly reduced.

As a further alternative, this valve embodiment could be used in conjunction with the valve of Figures 3 to 6 to provide enhanced isolation between the opening and the wound.

The aperture 320 provides a means for passage of fluid into and/or out of the bag.

Referring now to Figure 8, a further example of an embodiment of the present invention is shown. This embodiment is a variant of the embodiment of Figure 3, and like reference numerals refer to like parts. The device 110 of Figure 8

comprises, again, first and second chambers 114 and 116 and a closeable aperture 118 which, in this example, is in the form of zip fastener. The two chambers 114, 116 again are separated by a partition comprising two adjacent layers 120, 122 each of which has a respective slit 124, 126. The slits may be orientated in the same direction, but offset from one another although, as mentioned above, this is not absolutely necessary; the slits may simply be oriented in substantially the same direction. Again, the openings in the layers need not be by means of slits, but may be by any suitable shape of openings. Operation of the device is as described above with reference to Figure 3.

10

It will be understood that the present invention has been described above purely by way of example and modifications of detail can be made within the scope of the invention.

15 Each feature disclosed in the description and the claims and drawings may be provided independently or in any appropriate combination.

It will also be appreciated that features of one aspect of the invention may be applied to features of another aspect of the invention.

20

Claims

1. A lesion or fistula isolating bag, the bag defining a first chamber having a closeable entrance and a second chamber for application to a lesion or fistula
5 and wherein access to the second chamber is made through the first chamber via a valve, the valve being arranged to inhibit passage of fluid from the second chamber to the first, and to allow said access from the first chamber to the second, the bag further comprising a closure for said closeable entrance.
- 10 2. A bag according to claim 1, wherein the closeable entrance is sealable.
3. A bag according to claim 1 or claim 2, wherein said valve includes at least two members which extend inside the bag and, when the closure is in a closed state, said members close to form the valve .
15
4. A bag according to claim 1 or claim 2, , wherein the valve comprises a flexible partition dividing the first and second chambers (114, 116), the partition comprising first and second adjacent layers (120, 122), and wherein each layer includes an aperture (124, 126), the respective apertures being offset
20 one from the other.
5. A lesion or fistula isolating bag (110) comprising:
first and second chambers (114, 116), one of which has a closeable opening (118) for access, wherein the chambers are divided by a flexible partition, the
25 partition comprising first and second adjacent layers (120, 122), and wherein each layer includes an aperture (124, 126), the respective apertures being offset one from the other.

6. A bag according to claim 4 or claim 5 in which each aperture comprises a respective slit.
7. A bag according to claim 6 in which the slits extend generally parallel to one another.
8. A bag according to any one of claims 4 to 7, wherein the first layer is formed of a material which is heavier than the material of the second layer.
9. A bag according to any one of claims 4 to 8, wherein one layer is thicker than the other.
10. A bag according to any one of claims 6 to 9, wherein the offset between the slits is between 100 mm and 5 mm, preferably between 50 mm and 10 mm, more preferably between 30 mm and 15 mm.
11. A bag according to any one of claims 6 to 10, wherein the slits are between 80 and 300 mm long.
12. A bag according to any one of claims 4 to 11, wherein the bag comprises first and second bag portions, the first chamber being formed by the first bag portion and the second chamber being formed by the second bag portion.
13. A bag according to any one of the preceding claims, wherein said closeable entrance is located on an outer edge of the first chamber .
14. A bag according to any one of the preceding claims, wherein the closure is a zip fastener.

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15. A bag according to any one of claims 1 to 13, wherein the closure is a removable cover such as a lid.
- 5 16. A bag according to any one of the preceding claims, wherein the bag includes a further aperture for the passage of fluid between atmosphere and the device.
17. A bag according to claim 16, wherein the further aperture comprises a drain.
- 10 18. A bag according to any one of the preceding claims, wherein an outer surface of the second chamber is adherent.
- 15 19. A bag according to any one of the preceding claims, wherein the first chamber has at least one overall dimension approximately equal to 50 mm.
20. A bag for isolating a lesion or fistula comprising:
a vessel comprising a first wall of flexible material, the first wall including a first slit, and the vessel further including a closeable opening on a
20 second wall, the second wall being opposite the first wall;
a bag including a second slit;
wherein the vessel and bag are joined with one another such that the first and second slits are oriented in the same direction and are adjacent to, but offset from, one another and the join surrounds an area encompassing the first and
25 second slits.
21. A method of making a bag according to any one of claims 1 to 20, wherein the bag or bags are made from flexible polymers, for example, any of polyethylene, polyvinyl chloride and ethyl vinyl acetate.

13

22. A method of making a bag according to claim 12, wherein the join between the first and second bags is made by a welding process, for example, any of thermal, radio-frequency and impulse welding.
- 5 23. A device for isolating a lesion or fistula substantially as hereinbefore described and as illustrated in Figure 2, or in Figures 3 and 4, or in Figures 5 and 6, or in Figure 7.

FIG 1

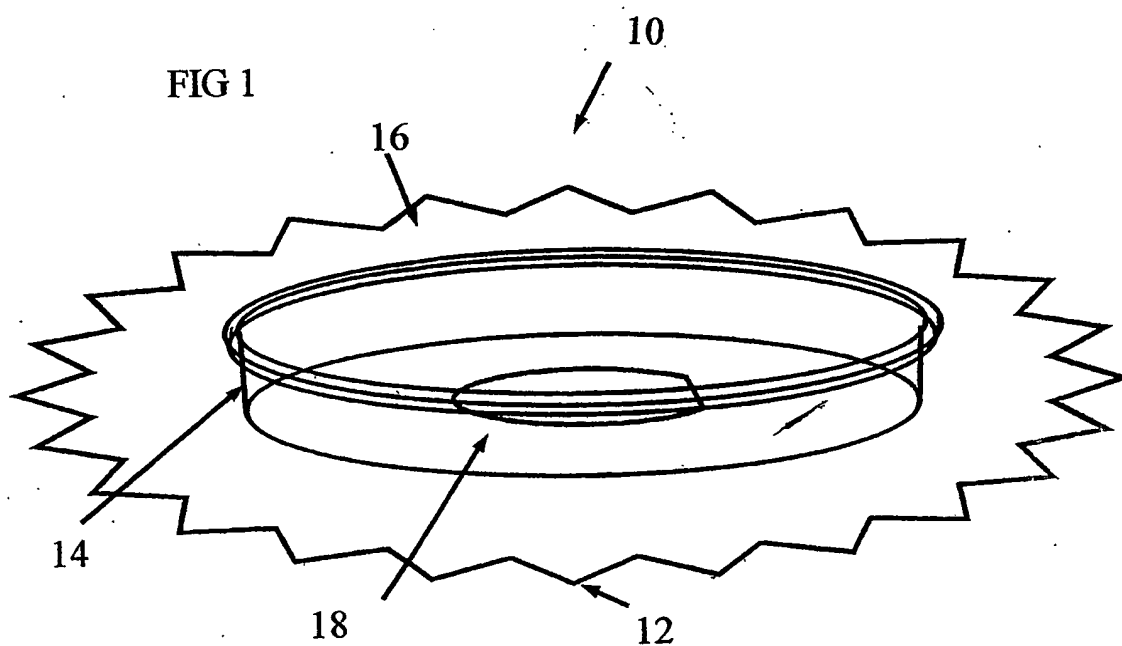
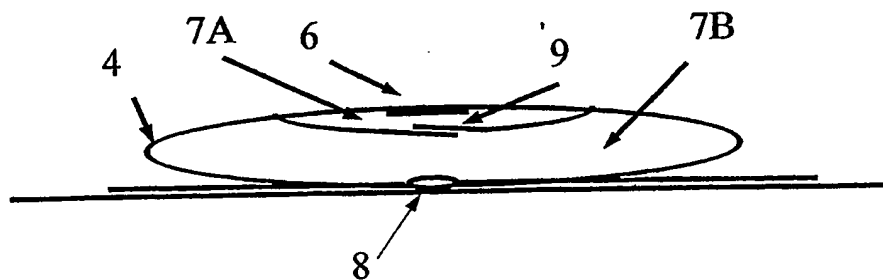


FIG 2.



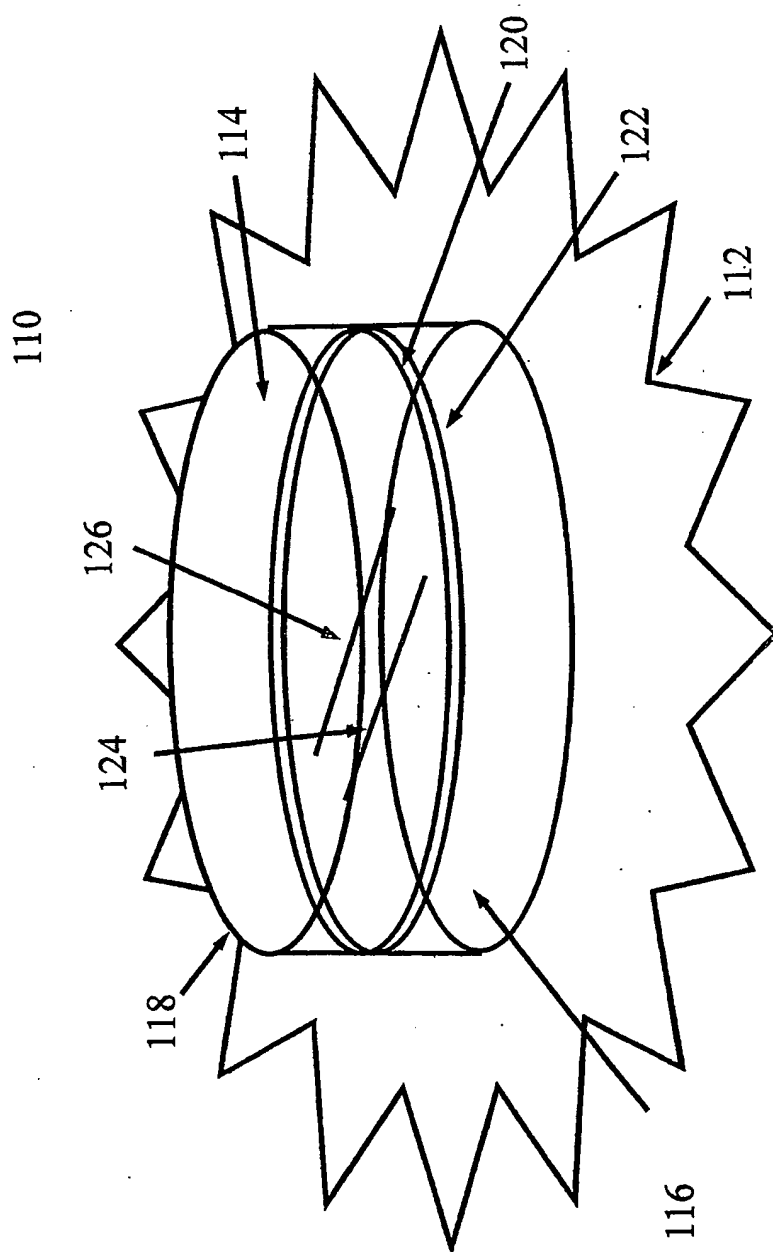


FIG. 3

FIG: 4A

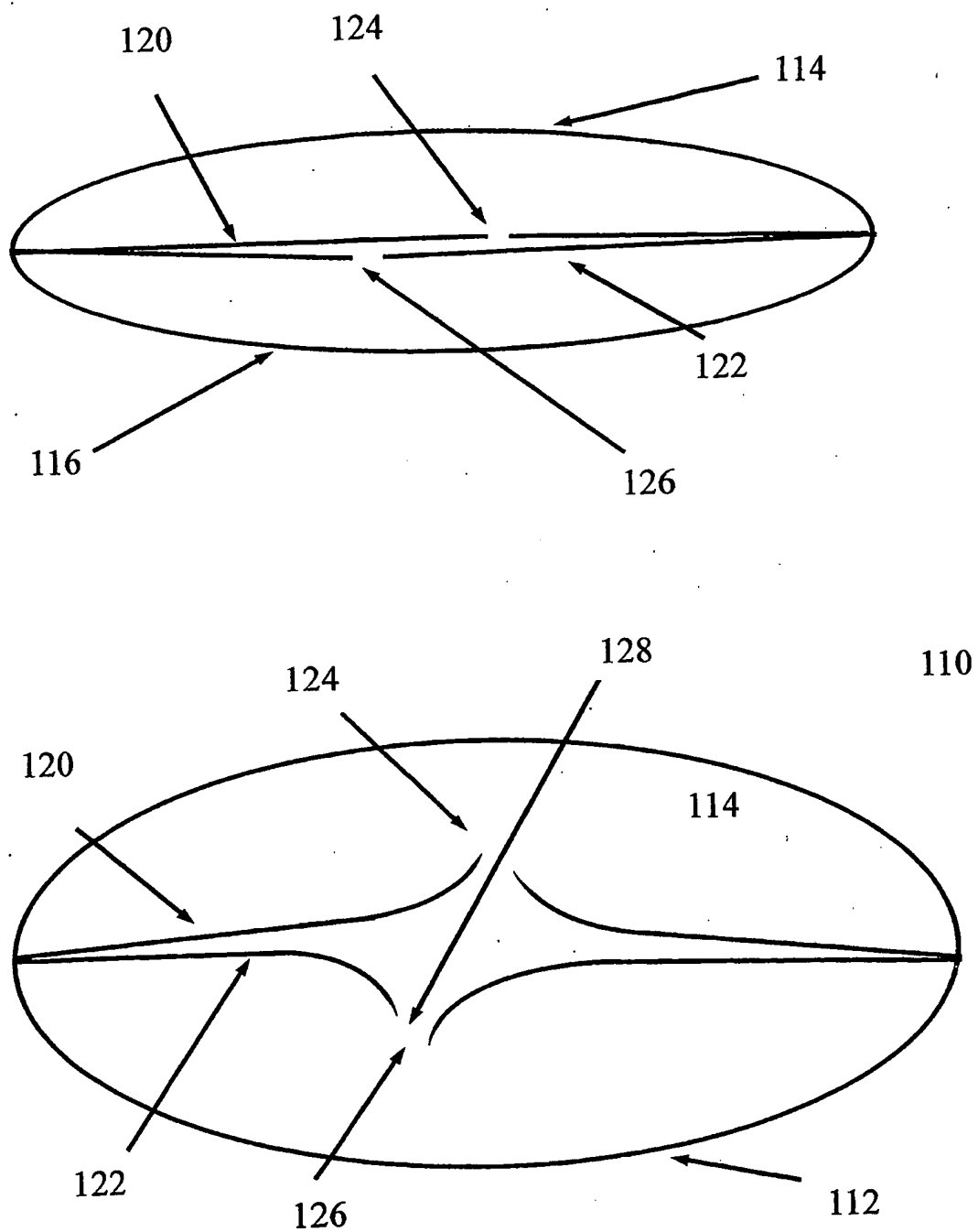


FIG: 5A

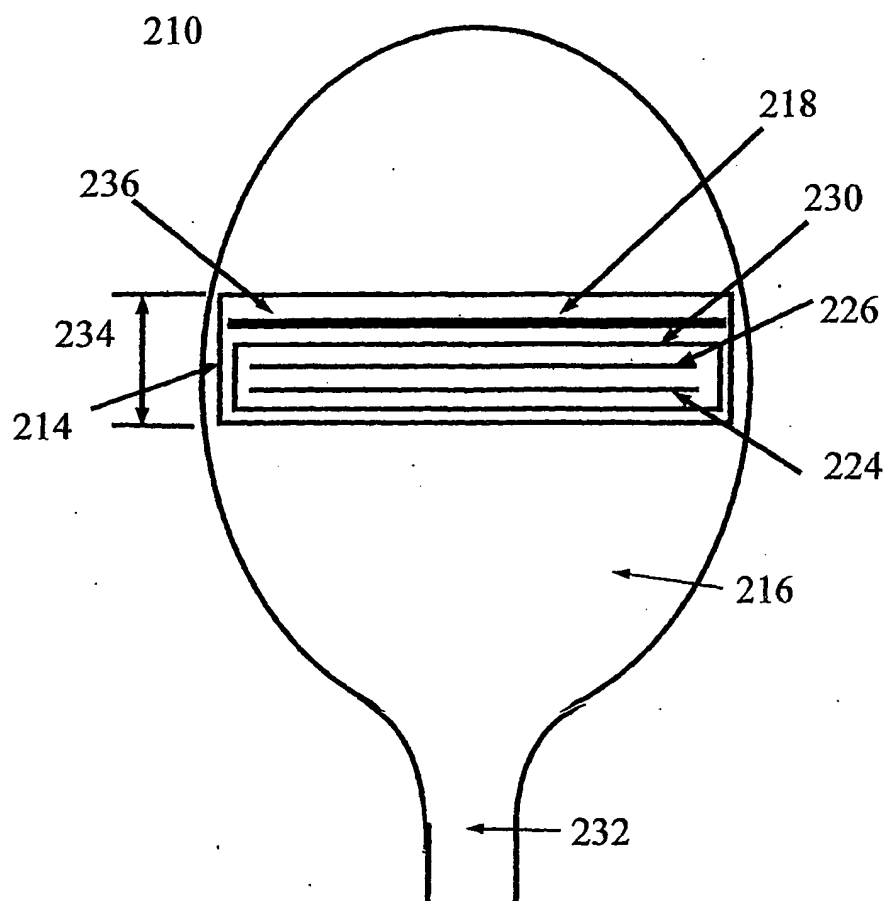
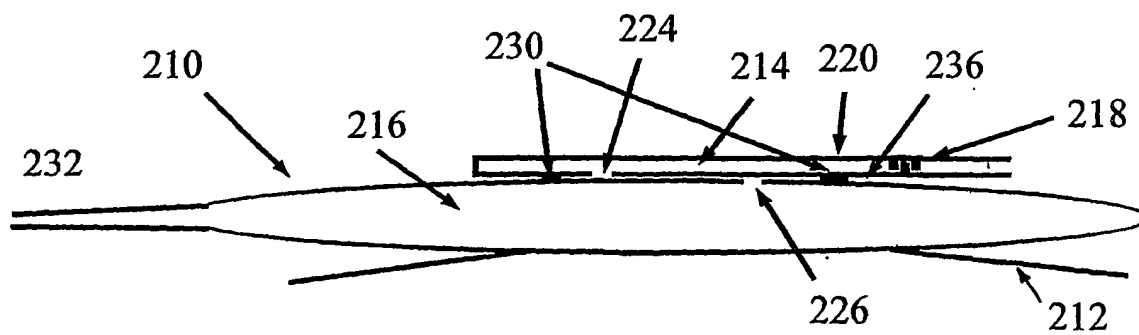
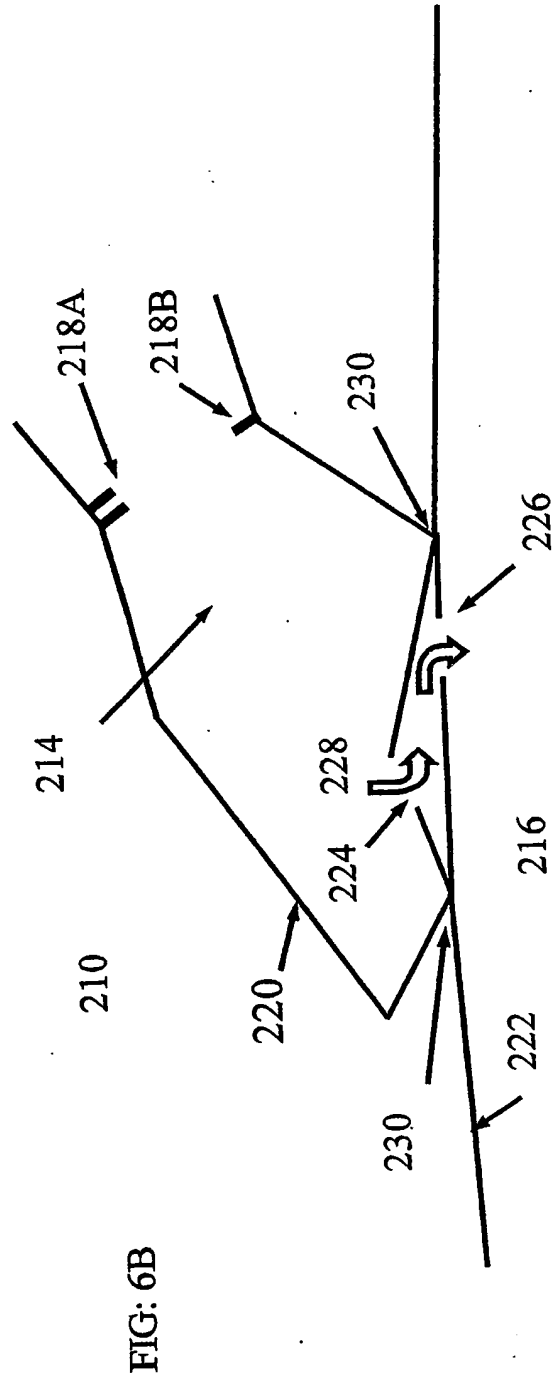
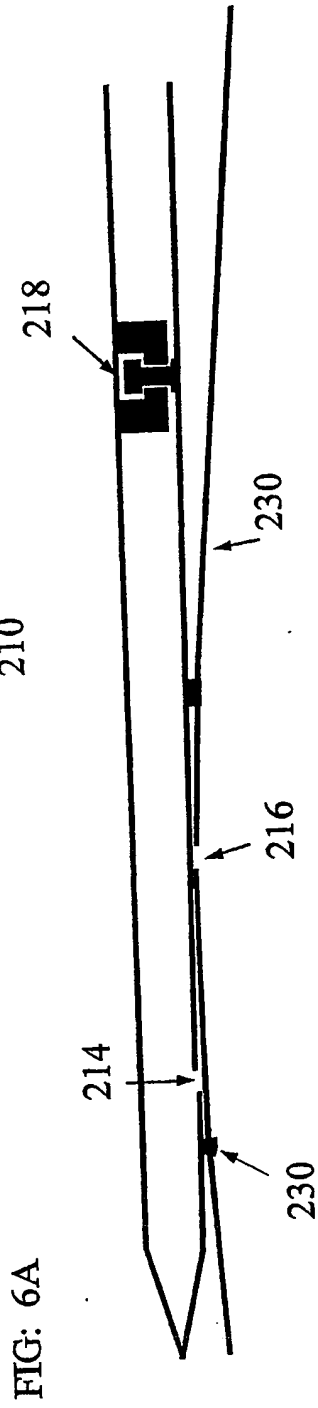


FIG: 5B





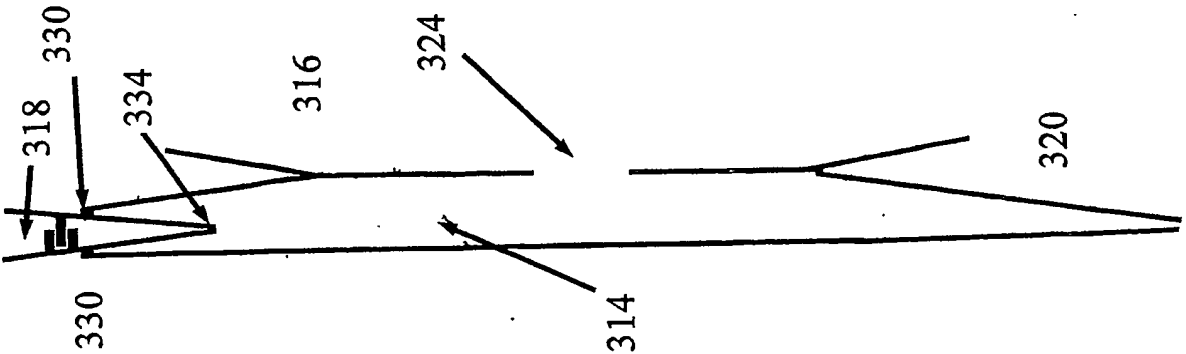


FIG: 7B

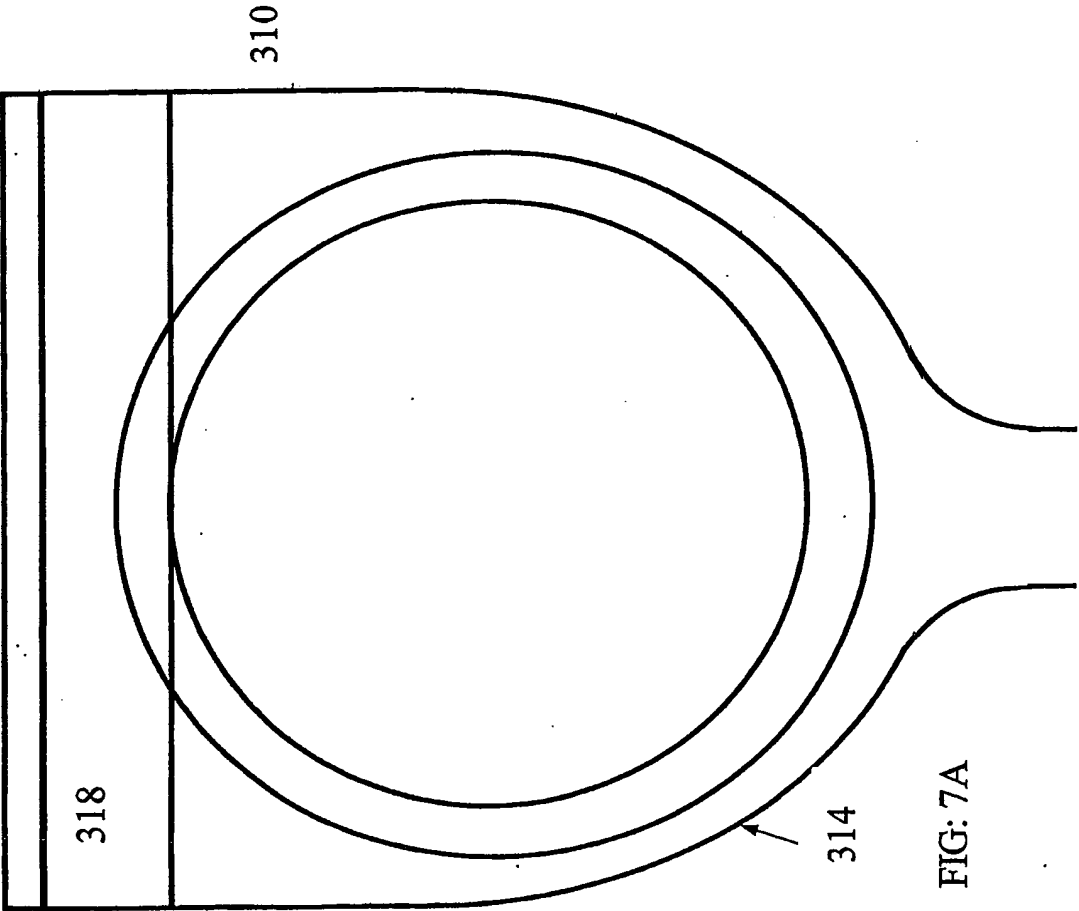
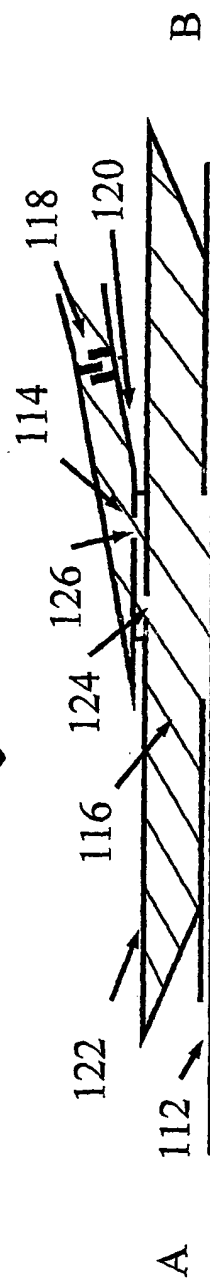
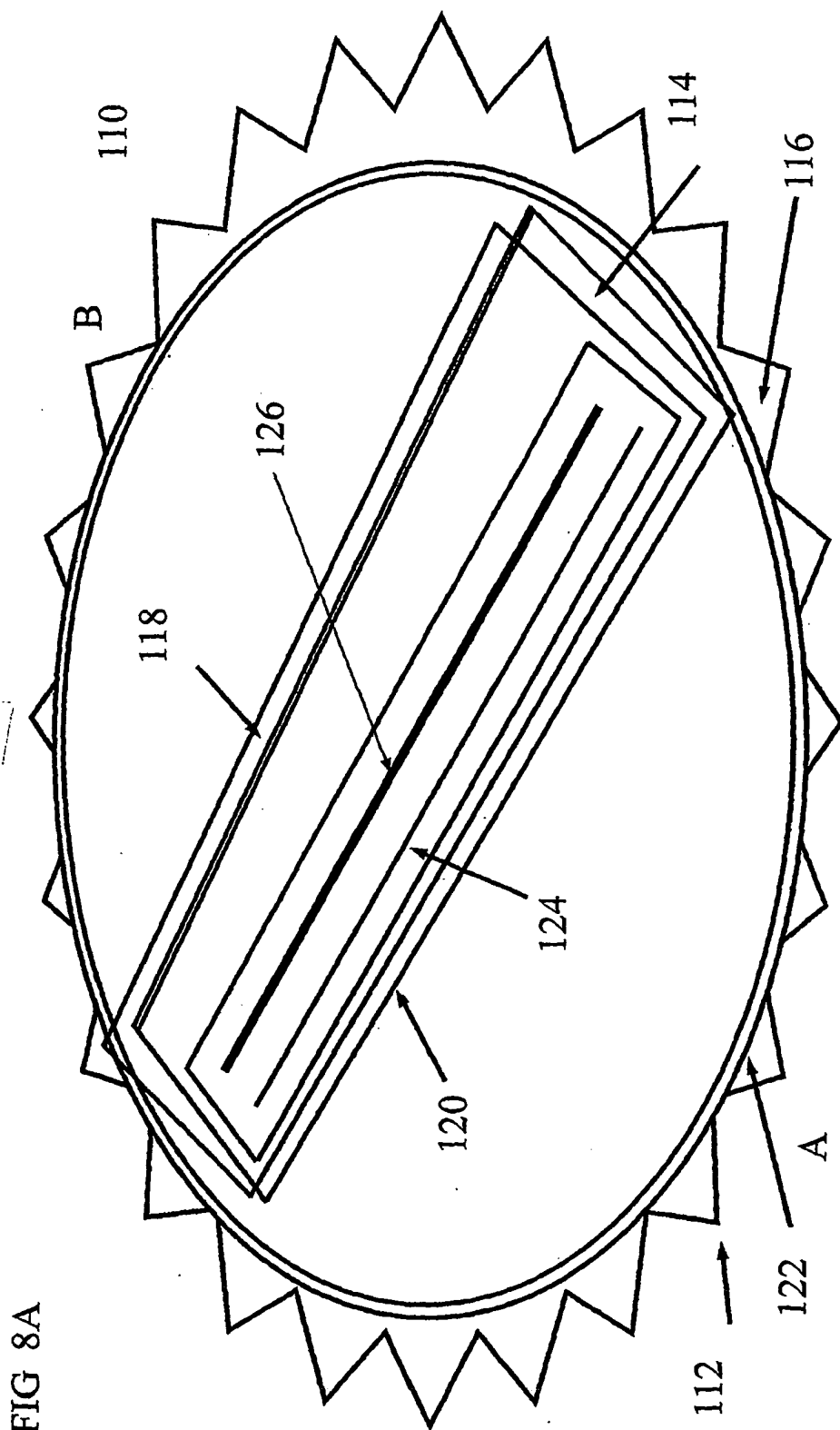


FIG: 7A



REPLACEMENT SHEET

FIG: 4A

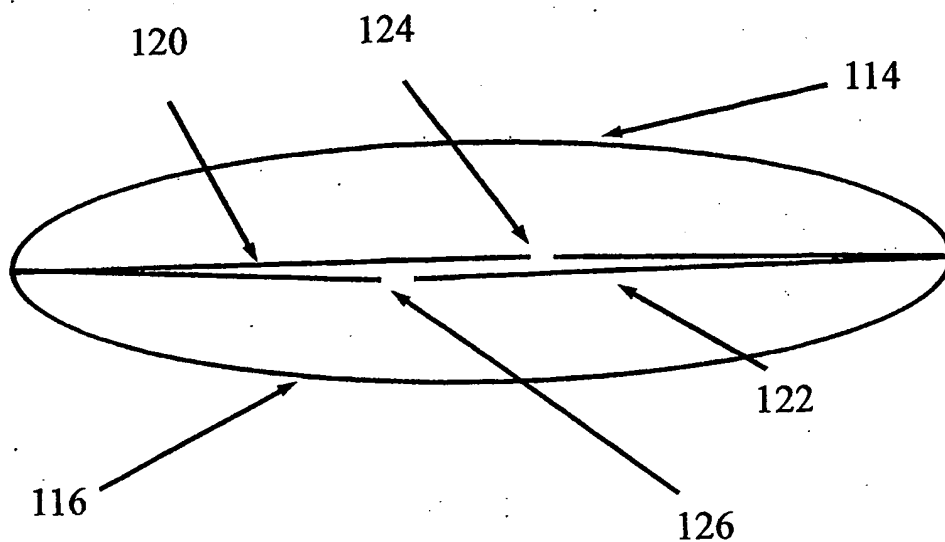
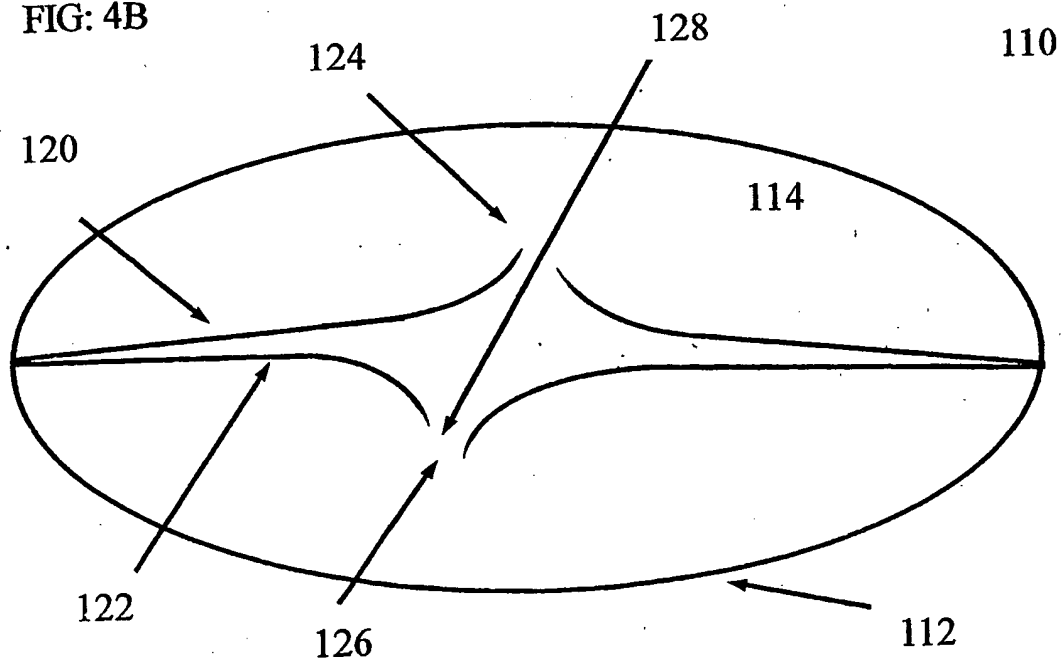


FIG: 4B



ANNOTATED SHEET SHOWING CHANGES

FIG: 4A

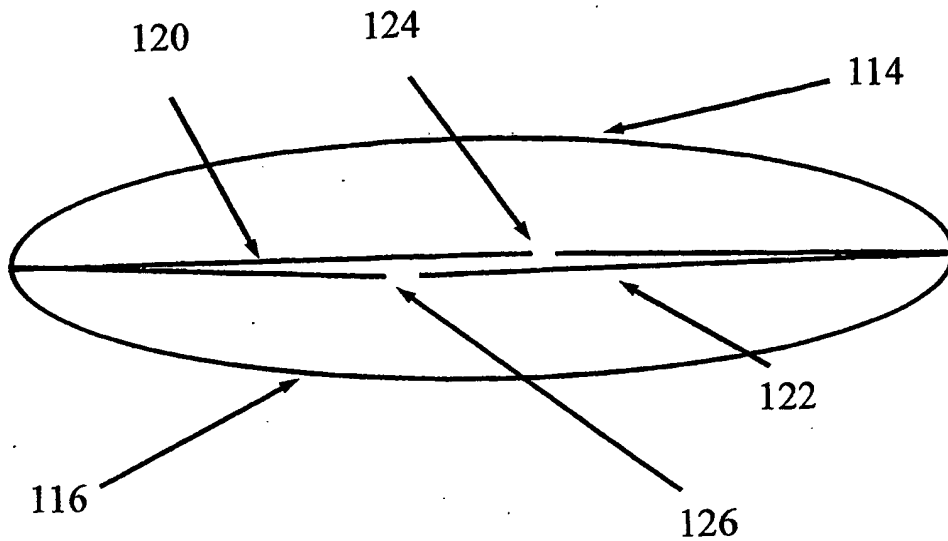


FIGURE LABEL ADDED

FIG: 4B

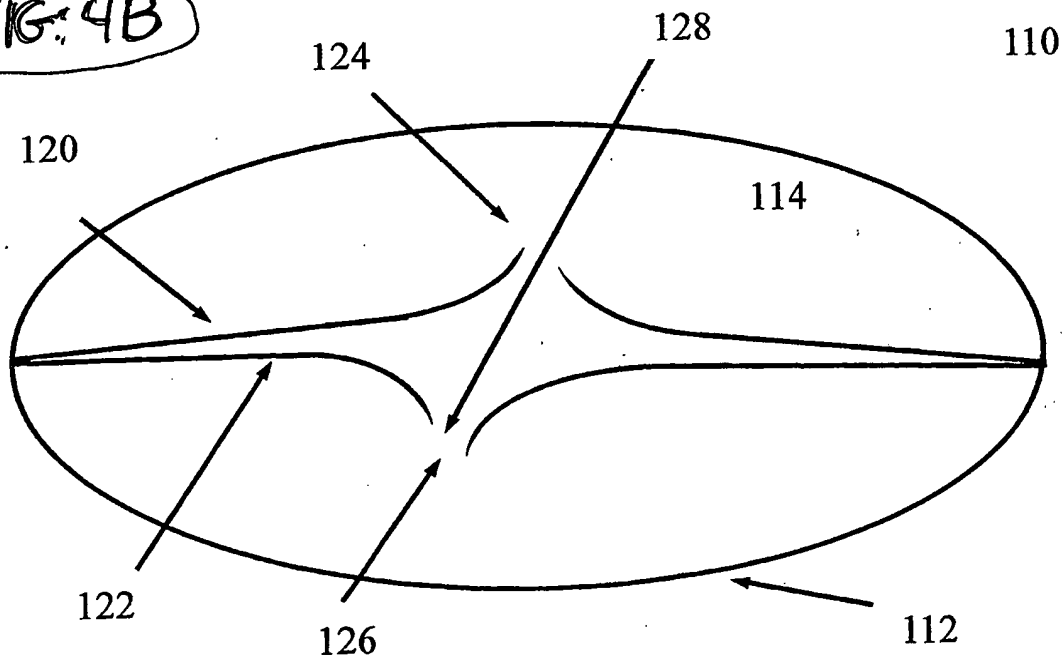


FIG 1

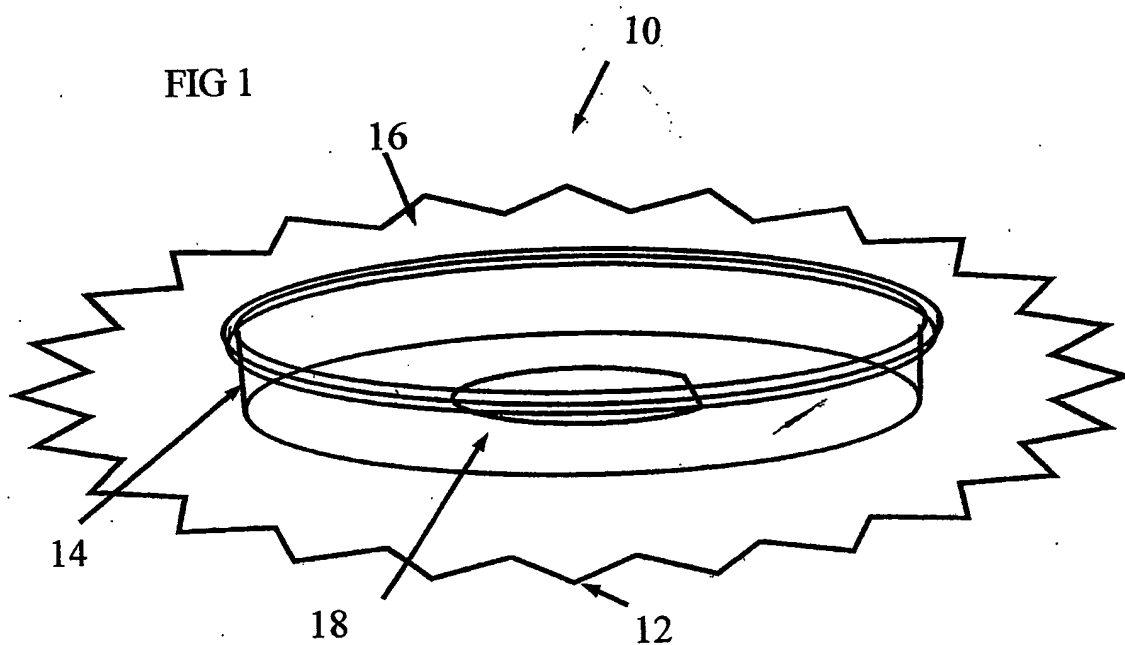
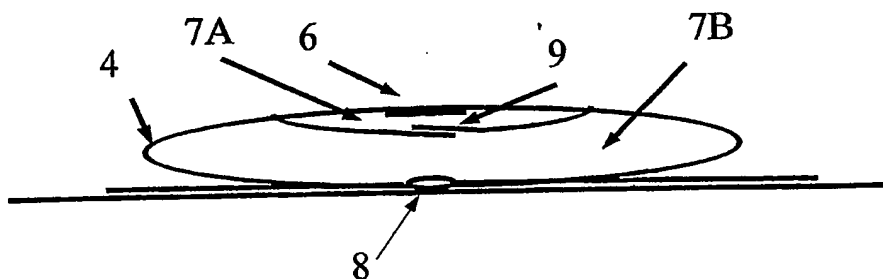


FIG 2.



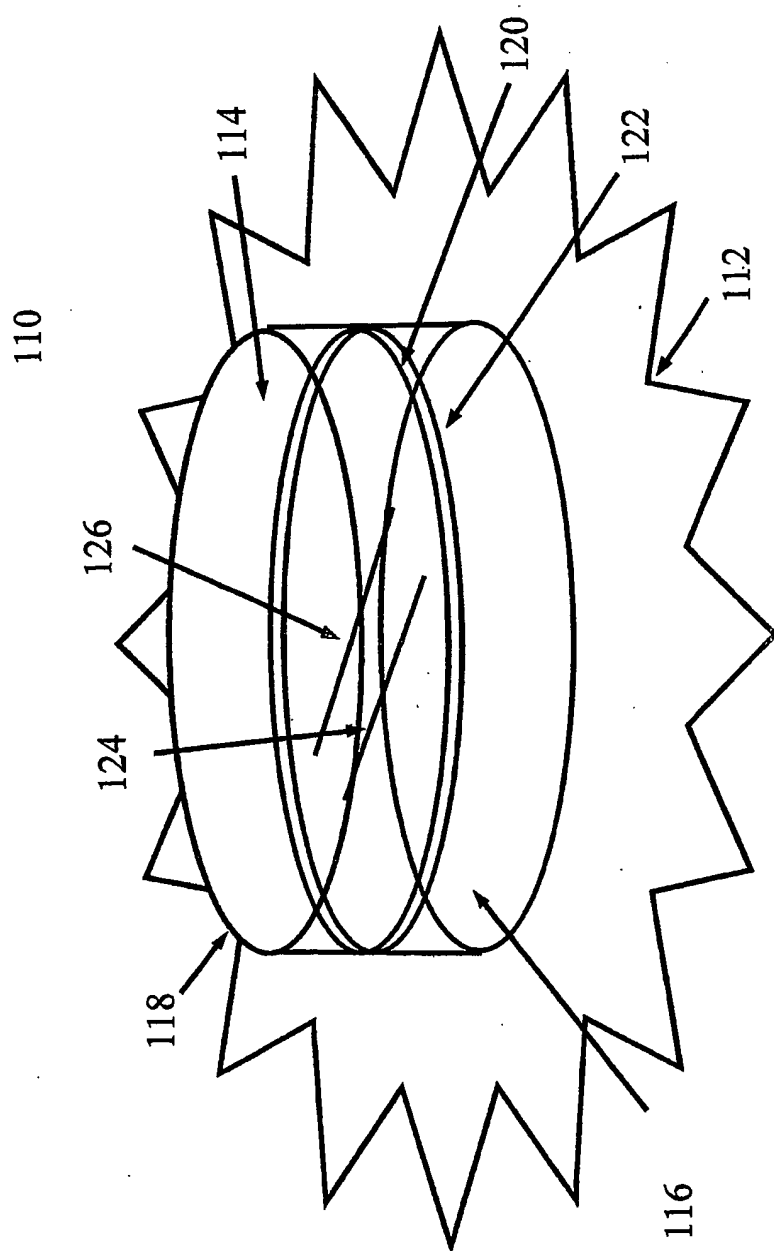


FIG 3

FIG: 5A

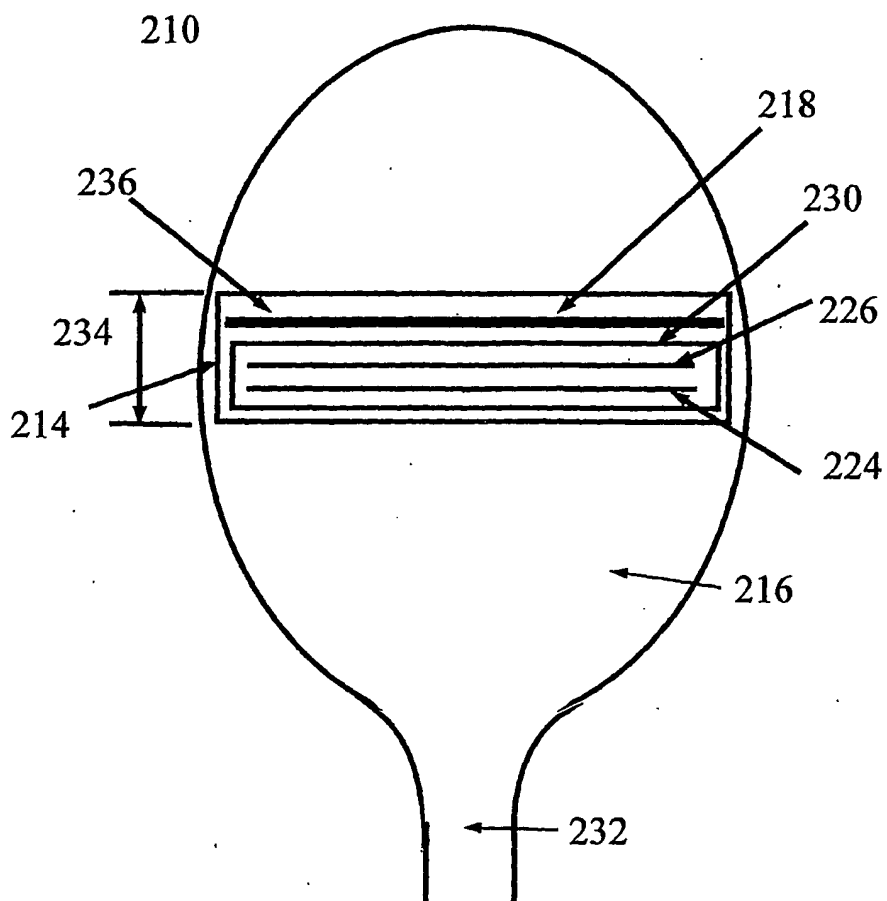


FIG: 5B

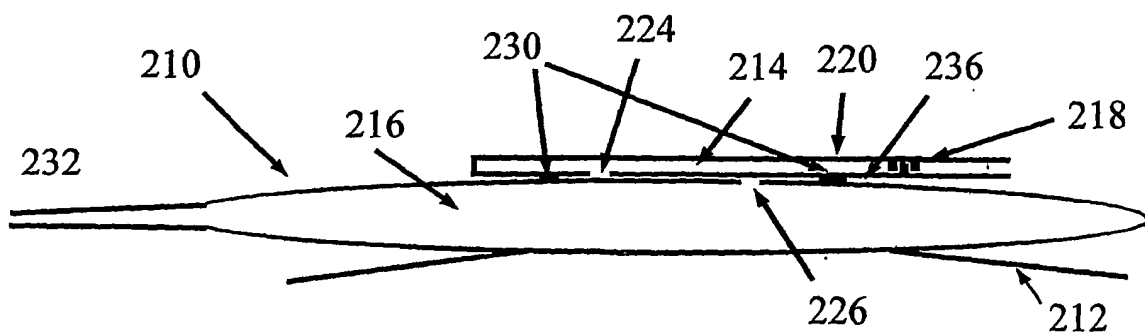


FIG: 4A

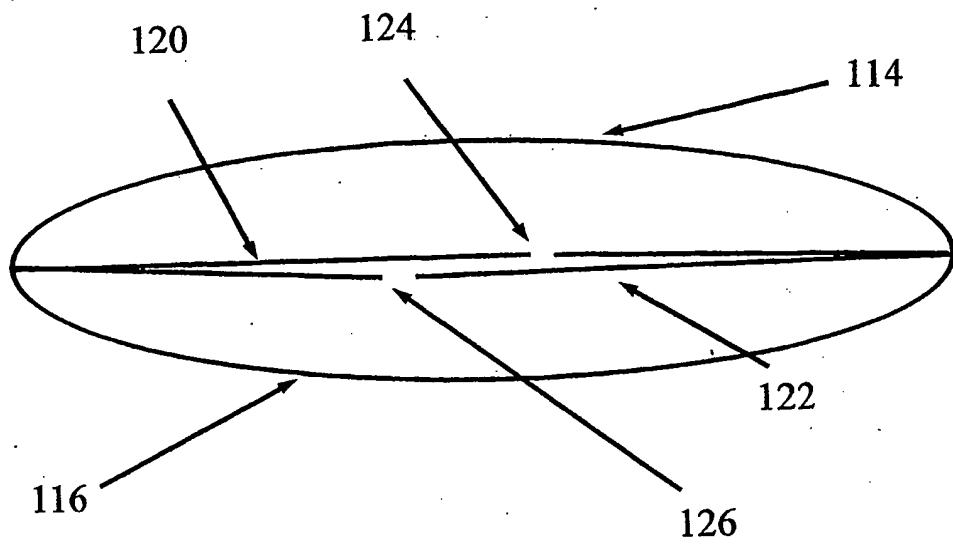
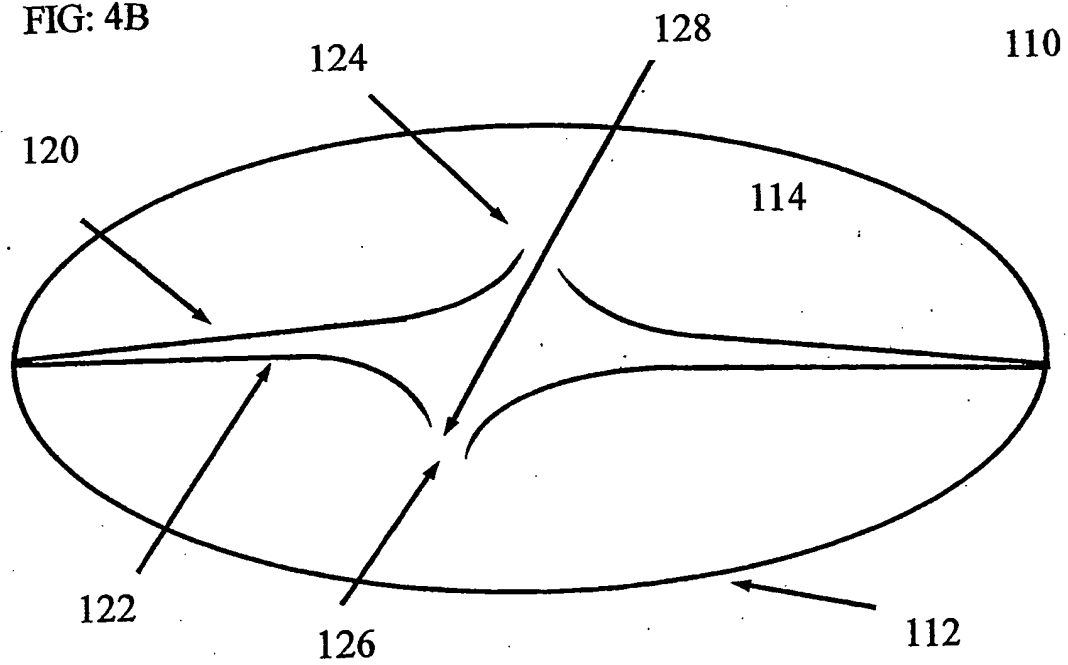
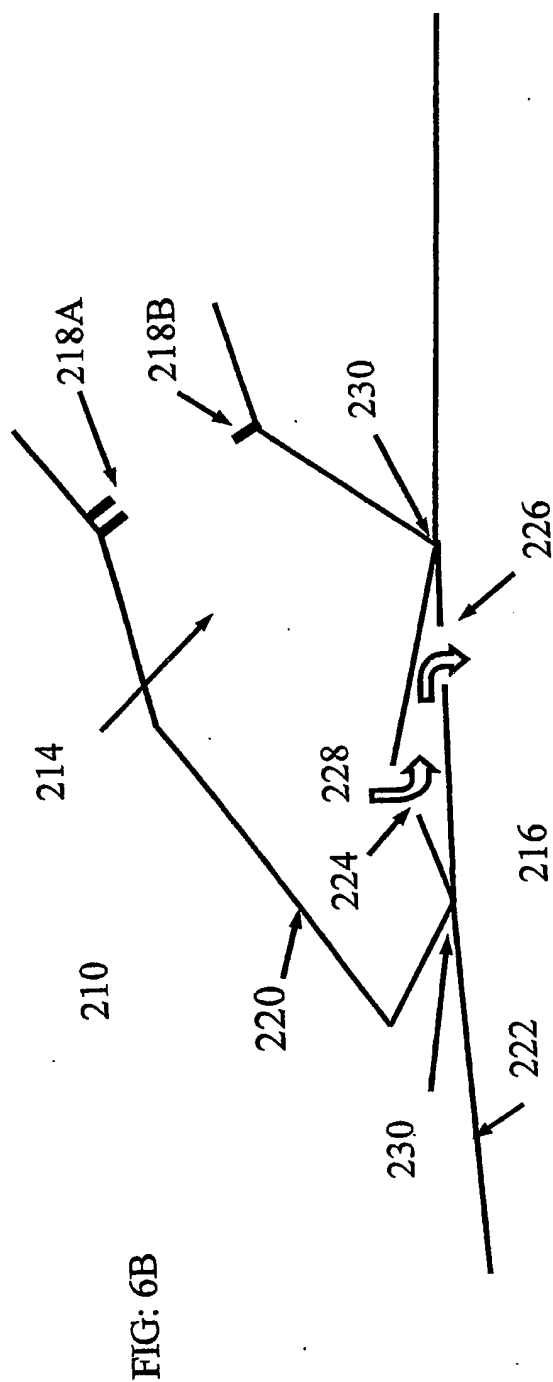
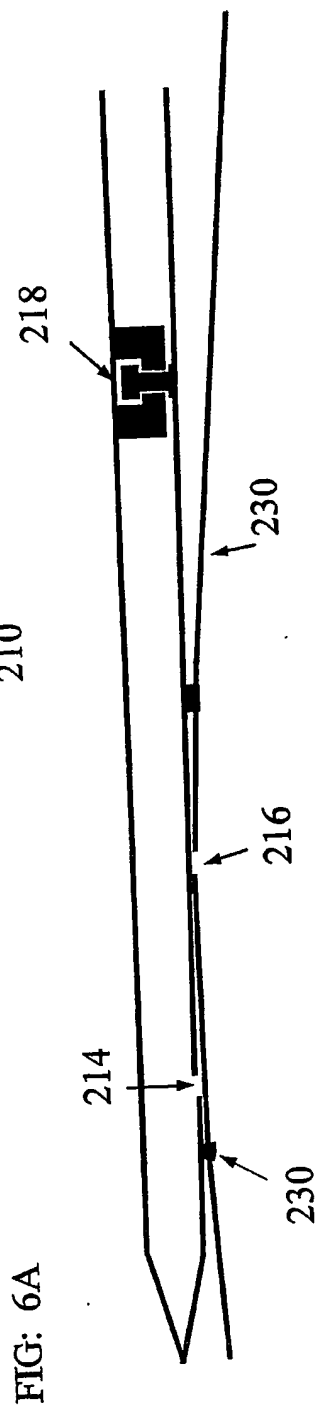


FIG: 4B





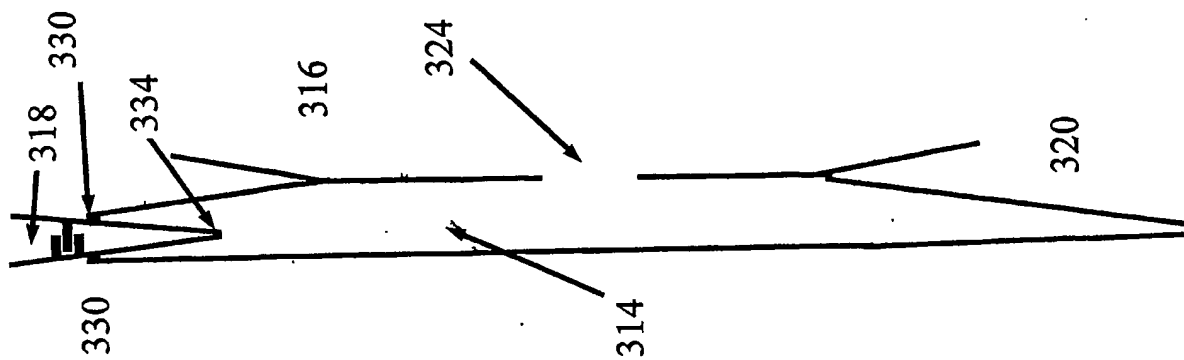


FIG: 7B

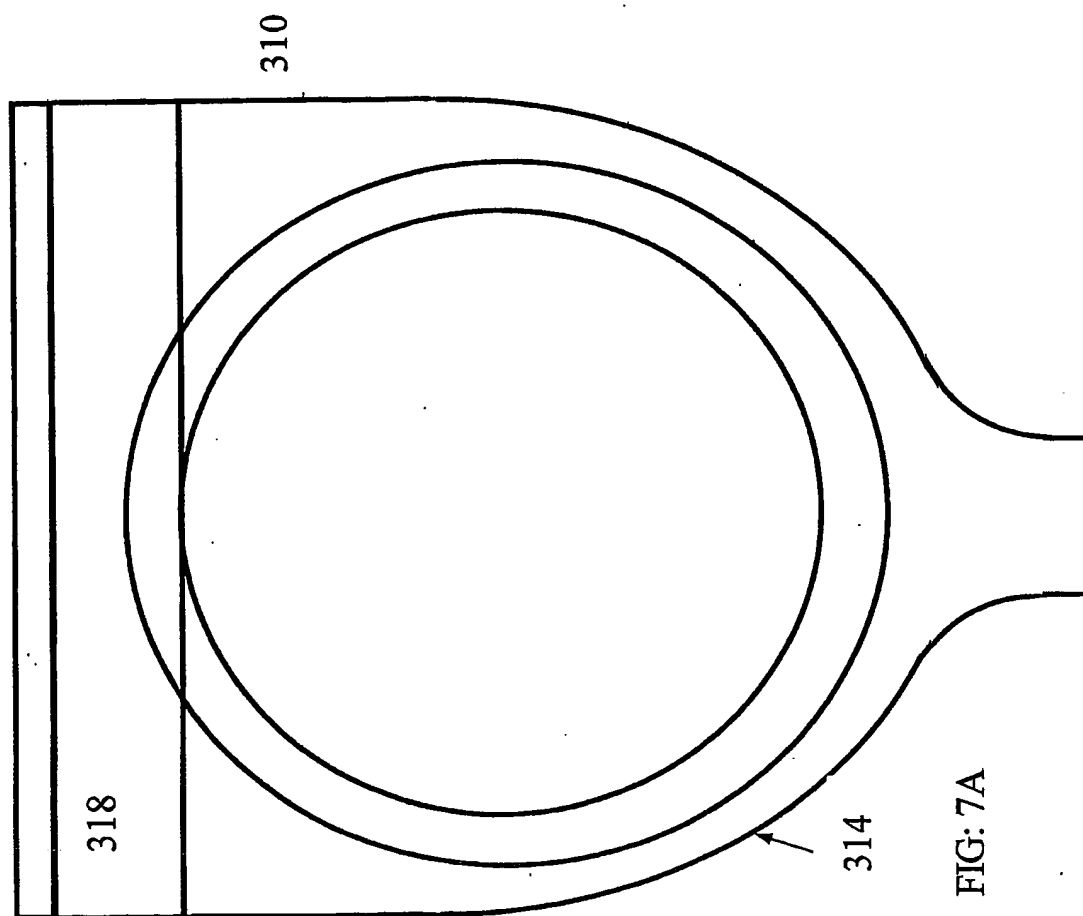
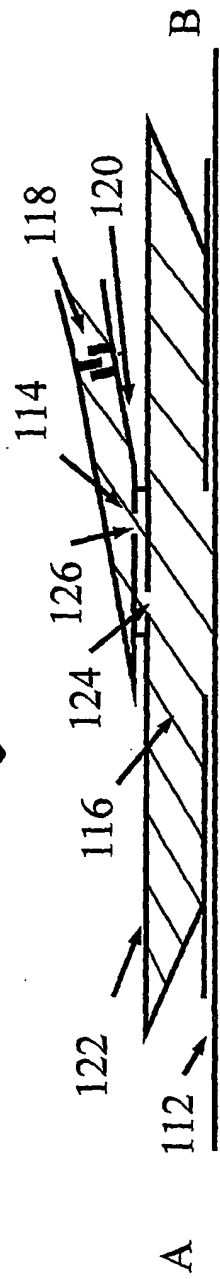
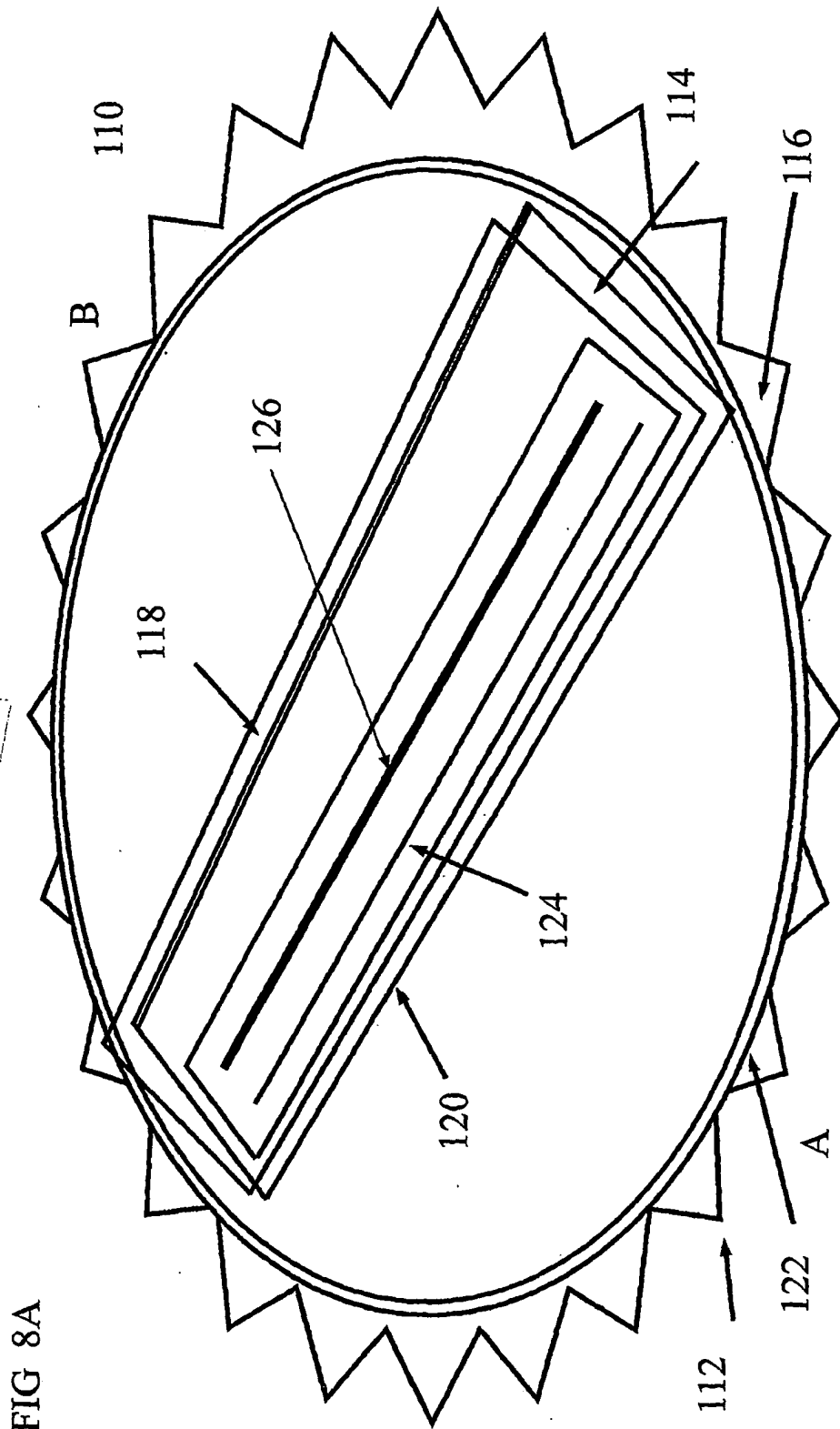


FIG: 7A



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (I)

(19) World Intellectual Property
Organization
International Bureau



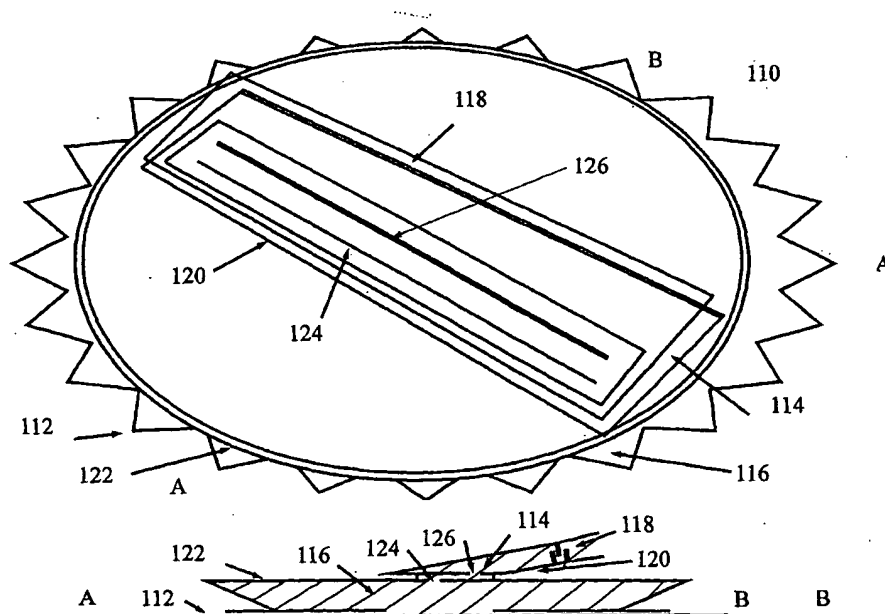
(43) International Publication Date
24 February 2005 (24.02.2005)

PCT

(10) International Publication Number
WO 2005/016158 A1

- (51) International Patent Classification⁷: **A61B 17/34**
- (21) International Application Number:
PCT/GB2004/003520
- (22) International Filing Date: 13 August 2004 (13.08.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0319139.2 14 August 2003 (14.08.2003) GB
- (71) Applicant (for all designated States except US): T.G. EAKIN LIMITED [GB/GB]; 15 Ballystockart Road, Comber, County Down BT23 5QY (GB).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): EAKIN, Thomas, George [GB/GB]; c/o T.G. Eakin Limited, 15 Ballystockart Road, Comber, County Down BT23 5QY (GB).
- (74) Agent: KILBURN & STRODE; 20 Red Lion Street, London WC1R 4PJ (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: OSTOMY/FISTULA BAG



(57) Abstract: A lesion or fistula isolating bag, the bag defining a first chamber having a closeable entrance and a second chamber for application to a lesion or fistula and wherein access to the second chamber is made through the first chamber via a valve, the valve being arranged to inhibit passage of fluid from the second chamber to the first, and to allow said access from the first chamber to the second, the bag further comprising a closure for said closeable entrance.

WO 2005/016158 A1

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P35147WO/MNM	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2004/003520	International filing date (day/month/year) 13/08/2004	(Earliest) Priority Date (day/month/year) 14/08/2003
Applicant T.G. EAKIN LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 8

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/003520

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/27468 A (MEDICAL CREATIVE TECHNOLOGIES) 19 October 1995 (1995-10-19)	1-3
A	claim 1; figure 3	4-23
A	GB 1 131 756 A (HOLLISTER INC) 30 October 1968 (1968-10-30) figures 2,4	1,5,20
A	WO 95/07056 A (BONADIO FRANK ; ENCORET LTD (IE)) 16 March 1995 (1995-03-16) figure 10	1
A	US 5 803 921 A (BONADIO FRANK) 8 September 1998 (1998-09-08) abstract	1
	----- -/-- -----	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

25 November 2004

Date of mailing of the international search report

02/12/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Korth, C-F

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/003520

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>EP 0 950 376 A (HAKKO ELECTRIC MACHINE WORKS C ; SHIMOMURA KAZUYUKI (JP)) 20 October 1999 (1999-10-20) abstract</p> <p>-----</p>	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB2004/003520

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9527468	A	19-10-1995	US 5813409 A	29-09-1998
			AU 2223195 A	30-10-1995
			AU 2240395 A	30-10-1995
			IE 71634 B2	26-02-1997
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WO 9507056	A	16-03-1995	AT 188364 T	15-01-2000
			AU 696289 B2	03-09-1998
			AU 7507494 A	27-03-1995
			CA 2171177 A1	16-03-1995
			DE 69422530 D1	10-02-2000
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			EP 0776180 A2	04-06-1997
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			EP 0888755 A1	07-01-1999
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			ES 2142404 T3	16-04-2000
			WO 9507056 A2	16-03-1995
			JP 3556670 B2	18-08-2004
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US 5803921	A	08-09-1998	IE 940150 A2	04-10-1995
			IE 940613 A2	04-10-1995
			IE 950055 A2	07-08-1996
			AT 164303 T	15-04-1998
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			DE 69501880 D1	30-04-1998
			DE 69501880 T2	23-07-1998
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			EP 0744922 A1	04-12-1996
			EP 0807416 A2	19-11-1997
			ES 2115365 T3	16-06-1998
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			NO 963421 A	14-10-1996
			NZ 279907 A	26-06-1998
			PL 315939 A1	09-12-1996
			RU 2137453 C1	20-09-1999
			ZA 9501378 A	24-10-1995
EP 0950376	A	20-10-1999	JP 3019150 B2	13-03-2000
			JP 11290327 A	26-10-1999
			EP 0950376 A1	20-10-1999

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB2004/003520

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0950376	A	US 6077288 A	20-06-2000

PATENT COOPERATION TREATY

Submission to
enter the
national stage
under 35 U.S.C.
§ 371.

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/003520

International filing date (day/month/year)
13.08.2004

Priority date (day/month/year)
14.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61B17/34

Applicant
T.G. EAKIN LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - Gitschiner Str. 103
D-10958 Berlin
Tel. +49 30 25901 - 0
Fax: +49 30 25901 - 840

Authorized Officer

Korth, C-F

Telephone No. +49 30 25901-574



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003520

10/568006

IAP20 Rec'd PCT/PTO 10 FEB 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/003520

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4-23
	No: Claims	1-3
Inventive step (IS)	Yes: Claims	4-23
	No: Claims	1-3
Industrial applicability (IA)	Yes: Claims	1-23
	No: Claims	

2. Citations and explanations

see separate sheet

10/568006

IP20 Res'd PCT/PTO 10 FEB 2006

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/003520

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial
applicability; citations and explanations supporting such statement**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-3 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document) a lesion (w) isolating bag defining a first chamber (18) having a closeable entrance (see page 7, lines 17-19) and a second chamber (C) and wherein access to the second chamber is made through the first chamber via a valve (32).